

### Open Discussion

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### Executive Summary

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This Rapid Review of the grey literature identified the following information with regard to open discussion/disclosure:

- What is best practice for open disclosure?
- What are the benefits of open disclosure?
- What are the barriers to open disclosure?
- How can open disclosure be measured for internal quality improvement?

#### Identified documents

Three guidance documents formed the basis of the information presented in this rapid review; these included the:

- Australian Open Disclosure Framework<sup>1</sup>
- Canadian Disclosure Guidelines<sup>2</sup>
- Clinical Excellence Commission Open Disclosure Handbook<sup>3</sup>.

Five other literature reviews<sup>4-8</sup> also provided relevant information.

The literature explains that defining the cases that warrant open disclosure present a challenge to healthcare systems due to the sparsity in clear definitions of what an 'event', 'error' or 'harm' is. We identified three guiding documents<sup>1-3</sup> from Australia and Canada that outline and provide definitions for which incidents require open disclosure. These are generally 'harmful incidents' where harm was caused to the patient and 'no harm incidents' where a patient safety incident reached the patient but no discernable harm resulted.

#### Types of incidents requiring open disclosure and timeliness of open disclosure

It was generally agreed that whenever a patient suffers harm, whatever the reason, the healthcare provider or organisation has an obligation to communicate to the patient about the harm and, if applicable, the event that led to the harm. This should be done in a timely manner as soon as the harm is discovered or detected. There is however data to suggest that a proportion of patients and families would prefer to learn about an incident only when its full extent is known.

#### The process of open disclosure

The principles for the process of open disclosure are consistent across the three guidance documents<sup>1-3</sup> identified and included some or all of the following steps:

- detecting and assessing incidents
- signaling the need for open disclosure
- preparing for open disclosure, engaging in open disclosure discussions
- providing follow-up
- completing the process
- maintaining documentation

Who should be involved in open disclosure was dependent on the type of disclosure required and informed by patient preference, setting, type of patient safety incident, severity of the harm and local policy.

The literature also presented information on how organisations can help meet the needs of healthcare providers and patients after a critical incident by ensuring effective support systems for clinician; guidelines on the management of critical incidents including immediate measures, disclosure standards and subsequent incident analysis; and educational interventions informing staff about the guidelines and support systems and training critical skills such as disclosure<sup>6</sup>.

### **Benefits of open disclosure**

The benefits of open disclosure in the healthcare setting are widespread across the organisation, the health professional and the patient, family and carer however these are also met with barriers which are presented at both an organisational level and an individual level.

### **Barriers to open disclosure**

The literature describes barriers to open disclosure from an organisational level and an individual level. The different barriers are outlined below.

#### Organisational barriers:

Culture has a major impact on the practice of disclosure. It has been the prevailing culture of infallibility among health professionals that leads to a lack of open communication, a lack of support from colleagues and supervisors, sanctions or disapproval from senior management, unrealistic performance expectations and ultimately to a 'culture of silence'<sup>6</sup>.

#### Individual barriers:

Four categories of individual barriers to open disclosure were identified by Manser (2011): Attitudinal barriers, helplessness, uncertainties and fears and anxieties. These barriers are seen to overlap with a lack of education and training and a lack of institutional support personally and through effective incident management systems<sup>5-6</sup>.

### **Measures of open disclosure for internal quality improvement**

The Australia Open Disclosure Framework (2013) provides a list of measures intended for internal use to facilitate quality improvement, monitoring and reporting of open disclosure to management. It is suggested that these measures be integrated with other clinical governance reporting systems and mechanisms and adapted to suit the local setting and context<sup>1</sup>.

- Number of open disclosure processes commenced in a reporting period
- Number of open disclosure processes concluded in a reporting period
- Number and percentage of open disclosure processes referred to mediation
- Number and percentage of open disclosure triggered by:
  - Complaints
  - clinical incident notification
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- Percentage of sentinel event formally disclosed
- Percentage of open disclosure vs. open disclosure requests through:
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  - complaints
- Results of patient surveys
- Results of staff surveys
- Percentage of clinicians trained in open disclosure
- Results of feedback to training
- Results of feedback to open disclosure

### **Conclusion**

In conclusion, a review on disclosure of patient safety incidents and adverse events, O'Conner et al (2010) state that to ascertain the outcomes desired by both the patients and the healthcare professionals, "closing the gap between aspirations and the reality of disclosure is challenging as it entails a change in attitude among healthcare professionals and a greater understanding from institutions about the effect on litigation. The evidence is limited but what there is suggests that full and frank disclosure offers potential benefits for improved patient experience and provider-patient relationships<sup>7</sup>."

## Objective

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A rapid review was undertaken to determine the following:

- What is best practice for open disclosure?
- What are the benefits of open disclosure?
- What are the barriers to open disclosure?
- How can open disclosure be measured for internal quality improvement?

## Methods

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A search was conducted in Google and Google Scholar using the following search terms: (open AND disclosure OR discussion) AND (health OR hospital).

## Results

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This rapid review identified eight documents which outlined best practice for open discussion. The results of this rapid review will refer to open discussion as open disclosure to reflect the language used in the literature.

As well as identifying what is seen as best practice for open disclosure and its benefits the rapid review identified barriers and measures for open disclosure for internal quality improvement.

### Best practice for open disclosure

#### *Types of incidents that require open disclosure*

The Australian Commission on Safety and Quality in Health Care<sup>1</sup> define open disclosure as “an open discussion with a patient about an incident(s) that resulted in harm to that patient while they were receiving health care...” However a review conducted by Birks et al (2014) looking at the exploration of the implementation of open disclosure of adverse events in the UK, they note that defining the cases that warrant disclosure present a challenge to healthcare systems due to the sparsity in clear definitions of what an ‘event’, ‘error’ or ‘harm’ is<sup>4</sup>. In addition to this, these keywords also only refer to events that come about when something is done, and do not encompass events that occur when something is not done<sup>4</sup>. “There does not appear to be any consensus about the obligation to disclose adverse events with minor consequences, despite the fact that most patients express the desire to be informed of these types of errors. It is proposed that the need for disclosure is proportionate and increases as the harm or risk of harm to the patient increases. Others have proposed the ‘view from below’, putting oneself in the patient’s position to determine how he or she would want the situation to be handled<sup>4</sup>.”

The search of the literature identified three guidance documents that outline when disclosure should take place.

The Canadian Disclosure Guidelines (2011) (Figure 1) suggest that: “Whenever a patient suffers harm, whatever the reason, the healthcare provider or organisation has an obligation to communicate to the patient about the harm and, if applicable, the event that led to the harm”<sup>2</sup>. The Clinical Excellence Commission (CEC) Open Disclosure Handbook (2014) use a similar diagram based on the Canadian model (Figure 2).

Figure 1. Canadian Disclosure Guidelines: Circumstances when disclosure should take place.

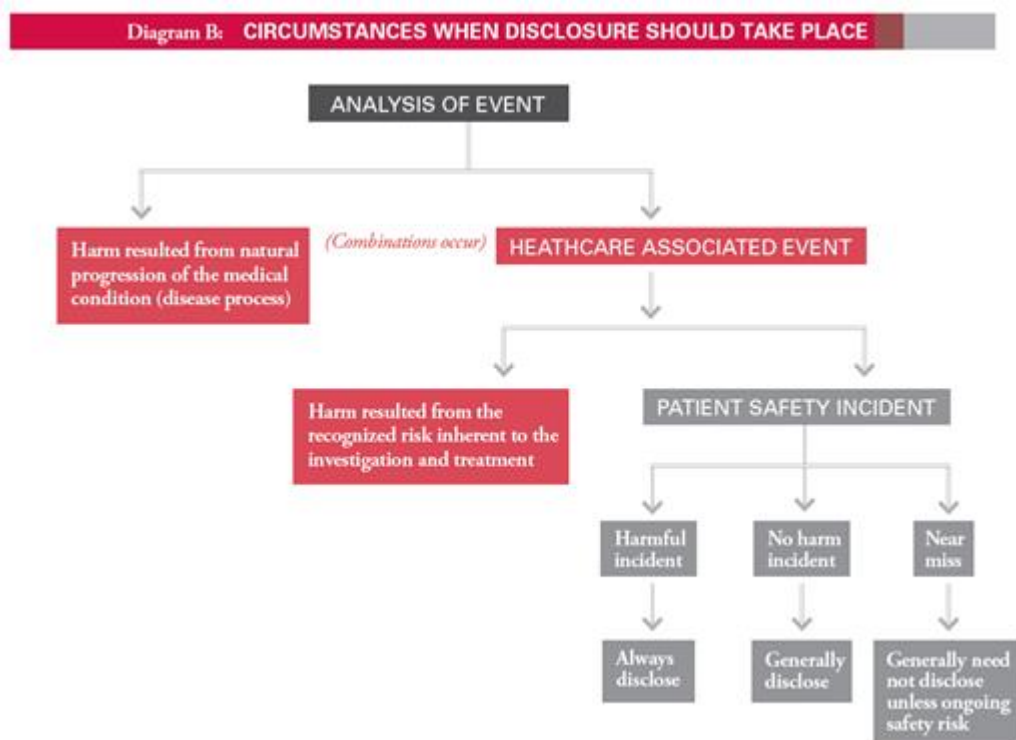
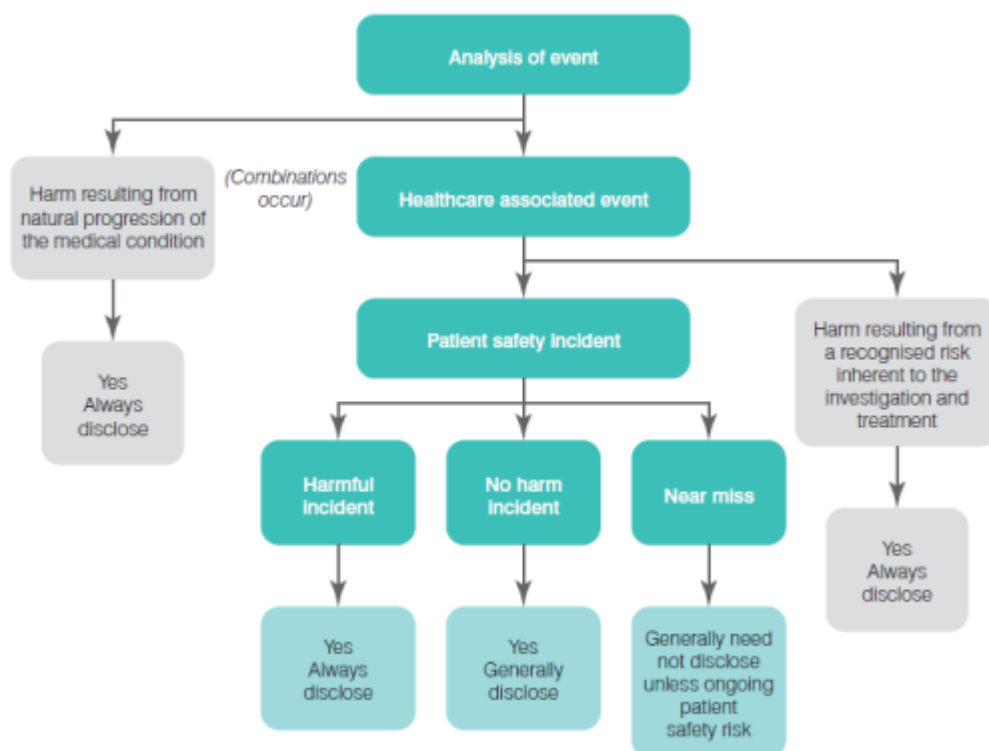


Figure 2. CEC Open Disclosure Handbook: When is Open disclosure necessary?



The Canadian Disclosure Guidelines (2011) as well as the CEC Open Disclosure Handbook (2014) use the following definitions for types of incidents to be considered for open disclosure:

- Harmful incident: A patient safety incident that resulted in harm to the patient.
- No harm incident: A patient safety incident which reached the patient but no discernible harm resulted
- Near miss: A patient safety incident that did not reach the patient

The Australian Open Disclosure Framework (2013) is also clear about when responses should be undertaken following particular incidents however is different to the Canadian and CEC guidelines in their explanation of incident types. They note that the “individual who detected the incident should make an initial assessment of the incident, usually in consultation with a senior clinician...consider the severity of harm and the level of response required...this will be determined by the effect, severity or consequence of the incident.” They also mention that “it is important to consider that patients, their families and carers can potentially suffer further emotional harm if post-incident communication is managed insensitively. A lower-level response should only be initiated if the risk of further harm (from not conducting higher-level open disclosure) is unlikely. Where uncertainty exists, a higher-level response should be initiated<sup>1</sup>.”

Figure 3 outlines the Frameworks potential responses to various situations and incidents and Figure 4 outlines the criteria for determining the appropriate level of response.

**Figure 3. Potential responses to various situations and incidents**

Incident type	Response
1. Harm from natural progression of condition or disease process <i>e.g. a treatment for cancer was unsuccessful</i>	Discuss and explain <i>(lower-level)</i>
2. Complication or natural disease progression a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (go to 3) <i>e.g. patient not adequately informed of the possibility of respiratory complications of general anaesthesia and feels that this would have altered their decision to proceed with treatment</i>	a. Discuss and explain <i>(lower-level)</i> b. Open disclosure <i>(higher or lower-level depending on severity)</i>
3. Patient harm/adverse event <i>e.g. adverse drug event (wrong dose medication)</i>	Open disclosure <i>(higher or lower-level depending on severity and impact on patient)</i>
4. Clinical ('no harm') incident: reaches patient but no harm <i>e.g. medication error (no/minimal effect on patient)</i>	Generally disclose <i>(lower-level)</i>
5. Clinical ('near miss') incident: does not reach patient <i>e.g. an intercepted wrong-patient biopsy</i>	Team decision based on: • context • circumstances • potential ramifications <i>(lower-level)</i>
6. Patient perception or report of harm <i>e.g. patient perception of delay in diagnosis resulting in poor patient outcome</i>	Discuss and agree on appropriate form of disclosure <i>(higher or lower-level)</i>

**Figure 4. Criteria for determining the appropriate level of response**

Incident type	Criteria
Lower-level response	1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required 4. No, or minor, psychological or emotional distress
Higher-level response	1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. Significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care, or transfer to intensive care unit) 4. Major psychological or emotional distress 5. At the request of the patient

### Timeframe and setting of open disclosure

There is consensus within the literature that open disclosure should take place immediately after the recognition of an adverse event occurring, prior to a detailed investigation, not too informally with the staff originally involved<sup>5-6</sup>. However in a literature review conducted by O’Conner et al (2010) they suggest that although most experts feel that disclosure should be conducted as soon as possible after an event has been discovered or detected, a significant proportion of patients and families would prefer to learn about an incident only when its full extent is known<sup>7</sup>.

The Canadian Open Disclosure Guidelines (2011) provide guidance on where the open disclosure meeting should be, to the extent possible:

- In person
- At a location and time of the patient’s preference
- In a private area to maintain confidentiality
- In a space that is free from interruptions

### The process of open disclosure

The disclosure process is generally consistent across the literature. The most common principles outlined include open and timely communication; acknowledgement; an apology or expression of regret; supporting, and meeting the needs and expectations of patients, their families and carers; supporting and meeting the needs and expectations of those providing health care; an explanation of systemic changes being made to prevent recurrence; integrated clinical risk management and systems improvement; good governance; and confidentiality<sup>1-3,5-7</sup>. Diagrammatic explanations of the process of open disclosure are presented in Figures 5 to 8.

Manser (2011) also outlines that the organisation can help meet the needs of healthcare providers and patients after a critical incident by ensuring effective support systems for clinician; guidelines on the management of critical incidents including immediate measures, disclosure standards and subsequent incident analysis; and educational interventions informing staff about the guidelines and support systems and training critical skills such as disclosure.

Figure 5. Canadian Disclosure Guidelines: The disclosure process

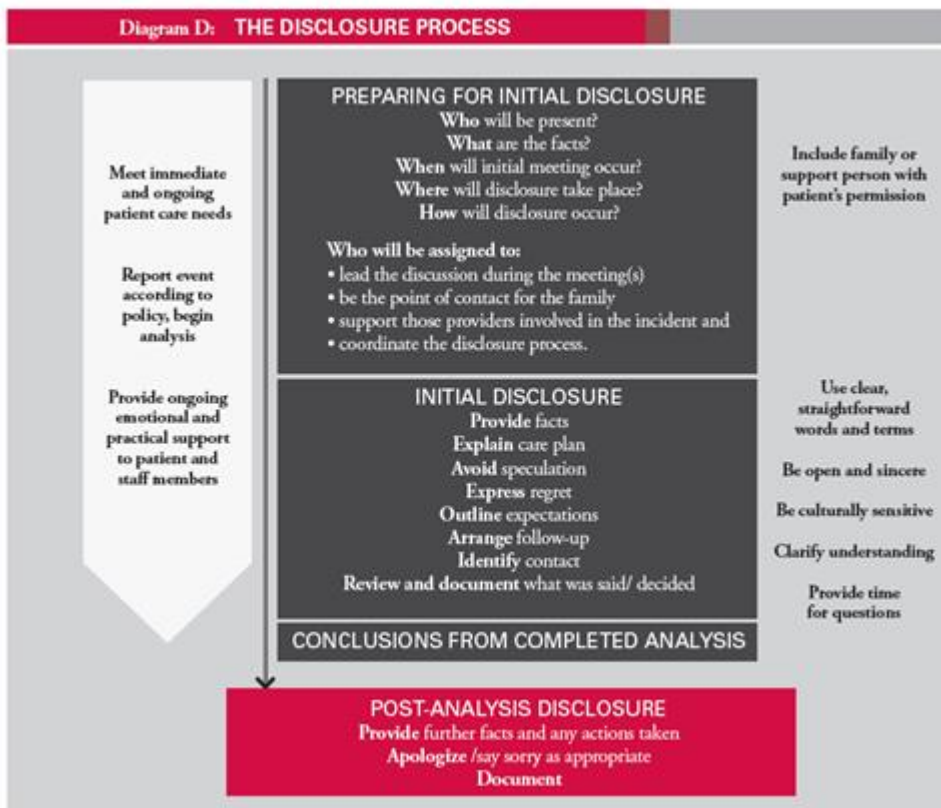




Figure 6. Australian Open Disclosure Framework: Key steps of open disclosure for high level responses

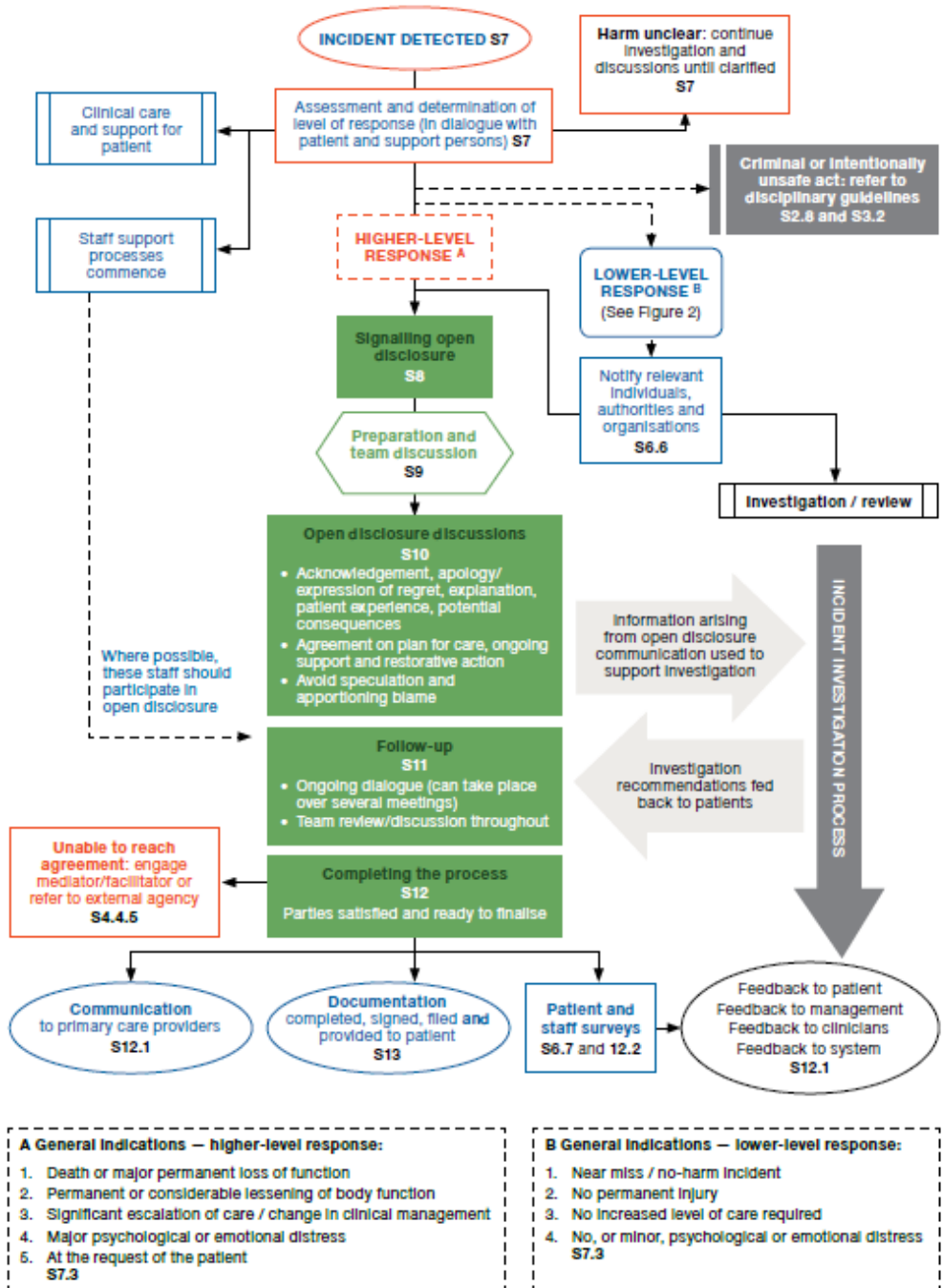


Figure 7. Australian Open Disclosure Framework: Key steps of open disclosure for low level responses

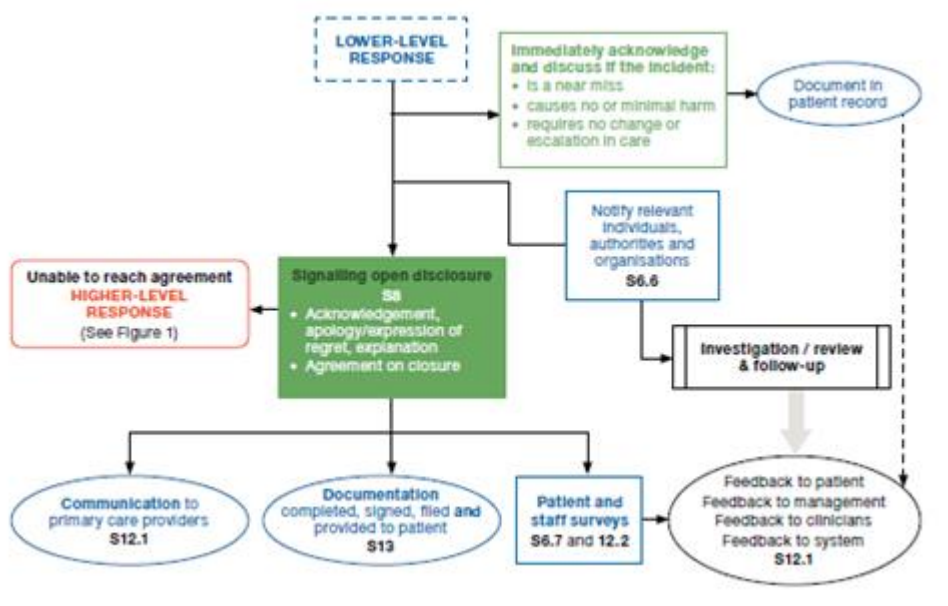
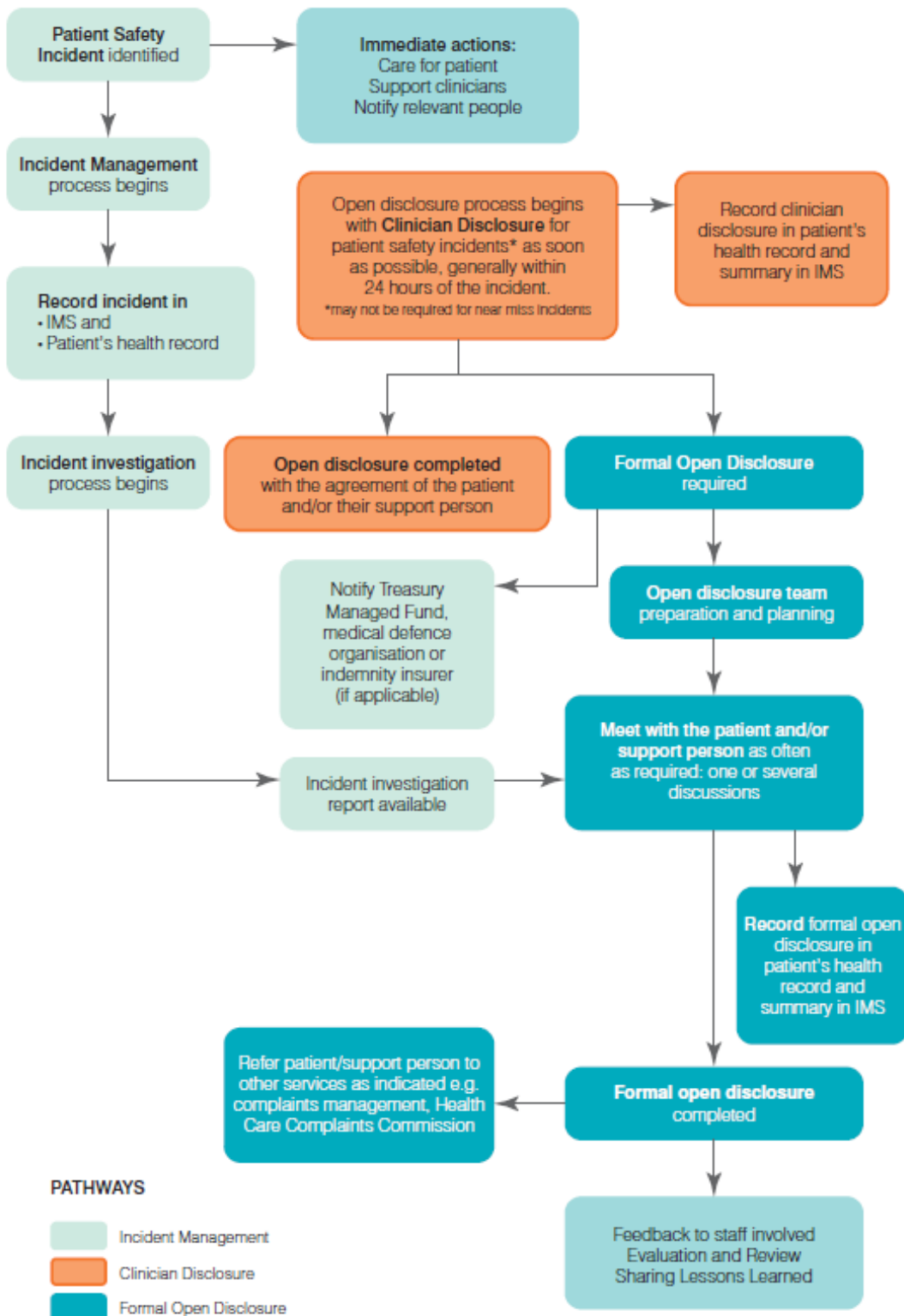


Figure 8. CEC Open Disclosure Handbook: Open disclosure flow chart

### OPEN DISCLOSURE FLOW CHART





## ***The open disclosure team***

Depending on the type of disclosure whether it is an initial clinician disclosure or a formal open disclosure meeting will influence the choice of who will participate. It should be informed by patient preference, setting, type of patient safety incident, the severity of the harm and local policy<sup>1-2</sup>.

The CDC Open Disclosure Handbook (2014) suggests that the initial clinician disclosure is an informal process involving:

- meeting with the patient and/or their support person(s) once the patient is removed from any harmful situation and has received treatment and support for the harm that may have occurred
- acknowledging the patient safety incident to the patient and/or their support person(s)
- explaining all known facts relevant to the incident, to provide context for the apology
- apologising for the occurrence of the event
- actively seeking input and feedback from and listening to the patient and/or their support person(s)
- consulting with the patient and/or their support person(s) on a plan for ongoing care if required, including the possible need for formal open disclosure
- providing contact names and phone numbers of people in the health service who are available to address concerns and complaints, including psychological and social support contacts.

Formal open disclosure is described as a structured process which follows on from clinician disclosure as soon as is practicable. It provides a format that facilitates effective and timely communications between the patient and/or their support person(s), clinicians, senior clinical leaders and the organisation<sup>3</sup>.

To enable this process, a multidisciplinary open disclosure team is activated before meeting with the patient and/or their support person. A senior clinician or manager who is trained as an open disclosure advisor guides this team through preparation, delivery and debriefing the formal open disclosure discussion with the patient and/or their support person<sup>3</sup>.

Formal open disclosure may be required for any patient safety incident, as determined by the Director of Clinical Governance, and/or the appropriate senior manager (for example, the facility, operations or health service manager), and the patient and/or their support person(s)<sup>3</sup>.

## **Benefits of open disclosure**

“Effective open disclosure is achievable through a combination of leadership; change management; and collaboration between stakeholders including patients, providers, institutions, professional associations, insurers and the legal profession<sup>3</sup>.” The benefit of systematically implementing open disclosure extends beyond the immediate context of a particular case and into service improvement more broadly<sup>8</sup>. Additional benefits may include:

- improved system responsiveness to patient needs
- improved clinical communication skills resulting in better care, diagnostic skills and patient-centred outcomes
- leverage for cultural reform through
  - embedding transparency and openness into healthcare services
  - flattening hierarchies, reducing barriers between disciplines and professions, and promoting a team-based ethic
- increased and improved notification, reporting and investigation of incidents (including the patient’s perspective on the trajectory of their care), resulting in more targeted quality improvement activity
- improved staff morale and retention
- strengthened public trust in healthcare institutions, including the patient–provider relationship<sup>8</sup>.

In a review conducted to inform the Australian Open Disclosure Framework (2011) open disclosure was found to create larger benefits for the health system and patients by fostering cultures of openness and trust<sup>8</sup>.

### ***For the patient, carer, family***

Benefits of open disclosure for the patient, carer and family have been documented and include:

- Allowing a patient to obtain timely and appropriate treatment to correct problems<sup>7</sup>
- Providing the necessary information to make informed decisions<sup>7</sup>

- Enables better-informed consent for any further treatment that may be required<sup>7</sup>
- Prevents needless worrying by patients about unexpected clinical outcomes<sup>7</sup>
- Disclosure may also permit a patient to obtain appropriate compensation for adverse outcomes<sup>7</sup>
- Ameliorating feelings of anger, guilt, grief or helplessness<sup>3</sup>
- Restoring trust in health care<sup>3</sup>
- Encouraging patients to participate in health care quality improvement processes<sup>3</sup>

Open disclosure, particularly a full apology that consists of an admission of responsibility; an expression of regret and action to remedy harm and prevent future occurrence – may moderate the recovery and health of patients after a critical incident<sup>6</sup>.

### ***For the healthcare professionals***

The benefits of open disclosure for the healthcare professionals are outlined in the CDC Open Disclosure Handbook (2014). These include:

- Enabling healthcare professionals to mitigate ongoing negative consequences of harmful incidents
- Enabling healthcare professionals to manage the stress and affective consequences of a harmful incident or complaint
- Ameliorating feelings of guilt and shame
- Facilitating a full and frank incident investigation which can be used to improve safety and quality
- Fulfilling professional, ethical and moral obligations to truthfully disclose information on harmful incidents.

### **Barriers to open disclosure**

The literature describes barriers to open disclosure from an organisational level and an individual level. The different barriers are outlined below.

#### Organisational barriers:

Culture has a major impact on the practice of disclosure. It has been the prevailing culture of infallibility among health professionals that leads to a lack of open communication, a lack of support from colleagues and supervisors, sanctions or disapproval from senior management, unrealistic performance expectations and ultimately to a 'culture of silence'<sup>6</sup>.

#### Individual barriers:

Four categories of individual barriers to open disclosure were identified by Manser (2011): Attitudinal barriers, helplessness, uncertainties and fears and anxieties. These barriers are seen to overlap with a lack of education and training and a lack of institutional support personally and through effective incident management systems<sup>5-6</sup>. Additional barriers include:

- Perceived medico-legal consequences of disclosure<sup>5,7,8</sup>
- Embarrassment at acknowledging an error<sup>5</sup>
- Uncertainty as to how much information should be disclosed<sup>5</sup>
- A lack of confidence in addressing sensitive issues<sup>7</sup>
- Concerns about preparedness for involvement in open disclosure<sup>8</sup>
- Tensions between the principles of openness and timely acknowledgement<sup>8</sup>
- The requirements for providers to take early advice from their insurers following a harmful incident<sup>8</sup>.

### **Measures of open disclosure for internal quality improvement**

The Australia Open Disclosure Framework (2013) provides a list of measures (Figure 9) intended for internal use to facilitate quality improvement, monitoring and reporting of open disclosure to management. It is suggested that these measures be integrated with other clinical governance reporting systems and mechanisms and adapted to suit the local setting and context<sup>1</sup>.

## Figure 9. Measures of open disclosure for internal quality improvement

- Number of open disclosure processes commenced in a reporting period
- Number of open disclosure processes concluded in a reporting period
- Number and percentage of open disclosure processes referred to mediation
- Number and percentage of open disclosure triggered by:
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- Percentage of open disclosure vs. open disclosure requests through:
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- Results of patient surveys
- Results of staff surveys
- Percentage of clinicians trained in open disclosure
- Results of feedback to training
- Results of feedback to open disclosure

## Conclusion: Implications for Monash Health

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This rapid review identified information relevant to what best practice is for open disclosure in health care, the benefits and barriers of open disclosure and potential measures of open disclosure for internal quality improvement.

Three guidance documents formed the basis of the information presented in this rapid review; these included the:

- Australian Open Disclosure Framework
- Canadian Disclosure Guidelines
- Clinical Excellence Commission Open Disclosure Handbook.

Five other literature reviews also provided relevant information.

The literature explains that defining the cases that warrant open disclosure present a challenge to healthcare systems due to the sparsity in clear definitions of what an 'event', 'error' or 'harm' is. We identified three guiding documents from Australia and Canada that outline and provide definitions for which incidents require open disclosure. These are generally 'harmful incidents' where harm was caused to the patient and 'no harm incidents' where a patient safety incident reached the patient but no discernable harm resulted.

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educational interventions informing staff about the guidelines and support systems and training critical skills such as disclosure.

The benefits of open disclosure in the healthcare setting are widespread across the organisation, the health professional and the patient, family and carer however these are also met with barriers which are presented at both an organisational level and an individual level.

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In conclusion a review on disclosure of patient safety incidents and adverse events, O'Conner et al (2010) state that to ascertain the outcomes desired by both the patients and the healthcare professionals, "closing the gap between aspirations and the reality of disclosure is challenging as it entails a change in attitude among healthcare professionals and a greater understanding from institutions about the effect on litigation. The evidence is limited but what there is suggests that full and frank disclosure offers potential benefits for improved patient experience and provider-patient relationships<sup>7</sup>."

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